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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/466,369 12/15/99 SINGH

S ACBI.031.01U

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HM12/1106

EXAMINER

SISSON, B

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 11/06/01

Handwritten initials

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/466,369

Applicant(s)

SINGH, SHARAT

Examiner

Bradley L Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 and 21 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on 06 August 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/466,369 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Still in view of Chenchik et al., Benson et al., Rothman et al., and Heller.
 5. Still discloses the use of labeled solid supports, or beads or particles, to which are attached chemical moieties. The type of label attached thereto encodes the chemical composition

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bound to the support. As set forth at page 157, right column, second paragraph: "Thus, while a library member itself may not be analyzable, it is possible to associate certain unique chemical markers or *tags* with that library member to specify identity."

6. Still does not disclose the use of lanthanides as labels or the combined use of lanthanides with fluorescent dyes or of performing multiplexing assays.
7. Chenchik et al., discloses performing multiplex assays with an array format and the use of a variety of dyes, including lanthanides (see columns 9 and 10).
8. Benson et al., teaches the use of multiple color fluorophores in the context of an automated DNA sequencing method wherein each color is representative of a specific nucleotide base. The concept of a multiplex reaction is discussed and that the four-color label approach to sequencing is conducted in a single tube (see column 1).
9. Benson et al., do not disclose using lanthanides as labels or in combination with fluorophores.
10. Rothman et al., column 10, fourth and fifth paragraphs, discloses the use of fluorophores in a variety of assay formats, stating: "The main types of fluorophores currently used as labels in such assays¹ are fluorescein, rhodamine, umbelliferone, and lanthanide chelates and the derivatives of these compounds." At lines 46-49 the wavelengths the above-identified fluorescent compounds is provided.
11. Rothman et al., do not suggest the use of both fluorescent dyes with lanthanide dyes.
12. Heller, column 5, second paragraph, like Rothman et al., speak in terms of the equivalency fluorescent compounds, identifying a variety of fluorescent compounds as well as

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lanthanide dyes. Also suggested in said paragraph is the use of "two or more fluorophores per probe."

13. In view of the totality of the prior art of record, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used lanthanide dyes as a detectable label in multiplex assays as the prior art clearly teaches the use of multiple fluorophores in a multiplex assay and the equivalency of lanthanide dyes to other known fluorophores. Said ordinary artisan would have also been motivated to have optionally combined more than one dye per solid support and that the different dyes need not all be lanthanides but could reasonable contain any of the known fluorophores identified in the art, including fluorescent dyes. Said ordinary artisan would have also been motivated, on the basis of commercial expediency and convenience, to have developed kits comprised of such particles, dyes, as well as labeled particles.

14. For the above reasons and in the absence of convincing evidence to the contrary, the invention of claims 1-18 is suggested by the prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

¹ Rothman *et al.*, column 10, lines 25-27, identifies the assays as being "immunoassays and other analytical assays

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organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L Sisson
Primary Examiner
Art Unit 1655

bls
November 5, 2001

involving binding.”